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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,279	05/15/2001	Theo Kirkland	TSRI 372.0 D2	3986

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/858,279

Applicant(s)

KIRKLAND ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,6-8,12,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,6-8, 12, and 21-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 2, 2004 has been entered.

### ***Amendment Entry***

2. The amendment filed February 2, 2004 has been entered. Claims 3, 6 and 12 have been entered. Claims 3, 6-8, 12 and 21-22 are under consideration in the office action.

### ***Withdrawal of Rejections***

3. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The rejection of claims 3, 6 and 12 under 35 U.S.C. 112, second paragraph;  
and
- b) The judicially created doctrine of obviousness-type double patenting rejection of claims 3, 6-8, and 21-22.

***Response to Arguments***

4. Applicant's arguments filed February 2, 2004 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

5. The rejection of claims 3, 6-8 and 12 under 35 U.S.C. 102(b) as being anticipated by Leturcq et al., is maintained for reasons already of record.

The grounds of the rejection are based upon Leturcq et al., teaching of monoclonal antibodies that bind to lipopolysaccharide binding protein (LBP), complexed to LPS, and denatured LBP. The monoclonal antibodies do not substantially inhibit LBP binding the LPS.

Applicants assert that with respect to antibody 18G4, Leturcq et al., do not disclose a binding specificity of 18G4 to denatured LBP, and that because independent claims 3,6 and 12 recite the limitation, the rejection should be withdrawn.

However, applicants appear to mischaracterize the teaching of Leturcq et al. Leturcq et al., statement is that one (8C9) of the three (monoclonal antibodies) recognizes denatured LBP only. The statement is interpreted as meaning that 8C9 recognizes and binds only to denatured LBP. The statement does not say that 18G4 does not bind denatured LBP. Rather the statement means that the other two antibodies, 1E8 and 18G4, bind to more than just the denatured LBP. Leturcq et al., teach three different epitope groups were elucidated and both 1E8 and 18G4 bind

Art Unit: 1645

native LBP and the complex of LBP bound to LPS meeting the requirements of the claims.

Applicants have presented no arguments that the 1E8 and 18G4 monoclonal antibodies of Leturcq et al., are incapable of having the binding abilities claimed in the prior art. Applicants have presented no scientific data stating that the 1E8 and 18G4 antibodies could not also bind denatured LBP. There is no evidence by applicant that epitope that allows binding to the native LBP is a different epitope when compared to the epitope that allows binding to the complexed LBP. It is noted that applicants mere assertion is not sufficient to over come the rejection.

Applicants' urge that Leturcq et al., does not teach monoclonal antibodies 4D7, 5C5, 6B6 or 24B7. However it is noted that the claims are not drawn to monoclonal antibodies 4D7, 5C5, 6B6 or 24B7. Rather the claims recite that the claimed monoclonal antibodies have binding specificity that is of monoclonal antibodies 4D7, 5C5, 6B6, 8C9, 18G4 or 24B7. The claim language is drawn to binding specificity and not to the actual antibodies. Moreover, the claim language recites the binding specificity using "or"; thus the claimed monoclonal antibody does not need to have the binding specificity of all the recited antibodies, just one of them.

Applicants comment that antibodies can be described in terms of their immunospecificity or binding specificity. The examiner agrees with the statement. It is noted that there are no structural limitations in the claims, rather the claims describe the claimed antibody only by its function, i.e., ability to bind and binding specificity. The

Art Unit: 1645

monoclonal antibody 18G4, meets those functional requirements, as evidenced by its binding abilities, therefore Leturcq et al., meet each and every limitation of the claims.

There is no structural difference between the claimed antibody and the prior art antibody in order to patentably distinguish the claimed invention from the prior art.

Because the prior art antibody is capable of performing the binding function, it meets the limitations of the claims. Prior art antibody 18G4 immunoreacts with lipopolysaccharide binding protein (LBP) but does not substantially inhibit LBP binding the LPS.

Monoclonal antibodies 1E8 and 18G4 taught by Leturcq et al., are the same antibodies which the instant application teaches as being able to inhibit the binding of LPS by CD14-expressing CHO cells, and shown to block the release of TNF from myeloid cells.

Therefore Leturcq et al., teach monoclonal abilities with the same functional abilities as those recited by the instant claims. The limitation that the monoclonal antibody include binding specificity to: LBP, denatured LBP, a complex containing LBP and LPS, and Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7 simply describes the binding specificity that the prior art antibody is capable of meeting. Since the Patent Office does not have the facilities for examining and comparing applicants' monoclonal antibody with the monoclonal antibody of the prior art reference, the burden is upon the applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed monoclonal antibody of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Art Unit: 1645


Applicants' appear to believe that the rejection of dependent claims 21-22 was in error. However, it is noted that claims 21-22 are ultimately dependant upon rejected claim 6. Moreover, there is nothing in the composition besides the antibodies, therefore the claims were rejected over Leturcq et al.

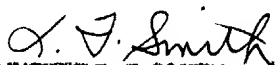
Applicants' arguments have not been found persuasive, therefore the rejection over Leturcq et al., is maintained.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines   
April 7, 2004

  
**LYNETTE R. F. SMITH**  
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